

**Michigan Office of Administrative Hearings and Rules  
Administrative Rules Division (ARD)**

MOAHR-Rules@michigan.gov

**REQUEST FOR RULEMAKING (RFR)**

**1. Department:**

Licensing and Regulatory Affairs

**2. Bureau:**

Bureau of Professional Licensing

**3. Promulgation type:**

Full Process

**4. Title of proposed rule set:**

Pharmacy – Program for Utilization of Unused Prescription Drugs

**5. Rule numbers or rule set range of numbers:**

R 338.3601 – R 338.3643

**6. Estimated time frame:**

12 months

**Name of person filling out RFR:**

Andria Ditschman

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**7. Describe the general purpose of these rules, including any problems the changes are intended to address.**

The purpose of the Pharmacy – Program for Utilization of Unused Prescription Drugs is to establish, implement, and administer a statewide unused prescription drug repository and distribution program consistent with the public health and safety, where unused or donated prescription drugs, other than controlled substances, may be transferred from an eligible facility or manufacturer to a pharmacy or a charitable clinic that elects to participate in the program, under section 17775 of the code, MCL 333.17775.

The rules were promulgated in 2014 and require a review and updates.

**8. Please cite the specific promulgation authority for the rules (i.e. department director, commission, board, etc.).**

Section 17775(12) of the code, MCL 333.17775, requires the Department in consultation with the Board to promulgate rules.

**A. Please list all applicable statutory references (MCLs, Executive Orders, etc.).**

MCL 333.16145 and MCL 333.17775; Executive Reorganization Order No. 1991-9, MCL 338.3501; Executive Reorganization Order No. 1996-2, MCL 445.2001; Executive Reorganization Order No. 2003-1, MCL 445.2011, and Executive Reorganization Order No. 2011-4, MCL 445.2030.

**B. Are the rules mandated by any applicable constitutional or statutory provision? If so, please explain.**

Yes, Section 17775(12) of the code, MCL 333.17775, requires the Department in consultation with the Board to promulgate rules.

**9. Please describe the extent to which the rules conflict with or duplicate similar rules, compliance requirements, or other standards adopted at the state, regional, or federal level.**

Each state establishes its own requirements with respect to the subject of these rules. The rules do not conflict with or duplicate similar rules, compliance requirements, or other standards adopted at the state, regional, or federal level.

**10. Is the subject matter of the rules currently contained in any guideline, handbook, manual, instructional bulletin, form with instructions, or operational memoranda?**

No. The subject matter of the proposed rules is not currently contained in any guideline, handbook, manual, instructional bulletin, form with instructions, or operational memoranda.

**11. Are the rules listed on the department's annual regulatory plan as rules to be processed for the current year?**

Yes, the rules are listed on the Department's annual regulatory plan.

**12. Will the proposed rules be promulgated under Section 44 of the Administrative Procedures Act, 1969 PA 306, MCL 24.244, or under the full rulemaking process?**

Full Process

**13. Please describe the extent to which the rules exceed similar regulations, compliance requirements, or other standards adopted at the state, regional, or federal level.**

The rules do not exceed similar regulations, compliance requirements, or other standards adopted at the state, regional, or federal level.

**14. Do the rules incorporate the recommendations received from the public regarding any complaints or comments regarding the rules? If yes, please explain.**

The Department will work with associations, related businesses, and lobbyists in preparing the proposed rules.

**15. If amending an existing rule set, please provide the date of the last evaluation of the rules and the degree, if any, to which technology, economic conditions, or other factors have changed the regulatory activity covered by the rules since the last evaluation.**

The rules were promulgated in 2014. There have been no technological factors, economic conditions or other factors that would necessitate amendment of the rules.

**16. Are there any changes or developments since implementation that demonstrate there is no continued need for the rules, or any portion of the rules?**

No, there are no changes or developments since implementation of the rules that demonstrate there is no continued need for the rules, or any portion of the rules.

**17. Is there an applicable decision record (as defined in MCL 24.203(6) and required by MCL 24.239(2))? If so, please attach the decision record.**

Yes